

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

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PBM PHARMACEUTICALS, INC. AND
CONCORDIA PHARMACEUTICALS
INC.

Plaintiffs,

Civil Action No. 3:14-cv-00016-GEC

v.

METHOD PHARMACEUTICALS, LLC
AND JOHN DOES 1-2

Defendants.

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AMENDED COMPLAINT

Plaintiffs PBM Pharmaceuticals, Inc. and Concordia Pharmaceuticals Inc. (“Plaintiffs”),
by and through their undersigned counsel, for their Complaint against Defendants Method
Pharmaceuticals, LLC and John Does 1-2 (“Defendants”), hereby allege and state the following:

INTRODUCTION

1. For nearly 80 years, Plaintiffs’ Donnatal® brand of pharmaceutical products has
helped improve the lives of individuals suffering from irritable bowel syndrome (IBS), a
condition characterized by abdominal pain, bloating, and irregular diarrhea or constipation.

2. Plaintiffs distribute and market Donnatal in two unique formulations: (1)
immediate release Donnatal Tablets and (2) fast-acting Donnatal Elixir, available in either grape
or mint flavor.

3. The active formulation in Donnatal comprises a combination of phenobarbital and belladonna alkaloids (“PBA”).

4. Defendants saw an opportunity to exploit the success of Donnatal by creating a knock-off PBA product that it is calling “Me-PB-Hyos.” Defendants falsely represent that Me-PB-Hyos is available in tablet and elixir form, and functions as a generic substitute for Donnatal.

5. Plaintiffs bring this action for injunctive relief to stop Defendants from falsely representing Me-PB-Hyos as a generic equivalent to Donnatal. Plaintiffs also seek damages resulting from Defendants’ unlawful conduct, including damages for harm to Plaintiffs’ reputation and goodwill.

THE PARTIES

6. Plaintiff PBM Pharmaceuticals, Inc. (“Plaintiff PBM”), conducting business under the name Revive Pharmaceuticals, is a Delaware corporation having its principal place of business in Charlottesville, Virginia. Plaintiff PBM is a specialty pharmaceutical company that focuses on revitalizing popular pharmaceutical products placed into lifecycle management by larger pharmaceutical companies. In addition, Plaintiff PBM is a 16.17% shareholder of Concordia Healthcare Corp., which is the ultimate parent company of Plaintiff Concordia Pharmaceuticals Inc. (“Plaintiff Concordia”). Plaintiff PBM provides certain services to Concordia Healthcare Corp., including receipt, acceptance and processing of orders, billing of customers, collection of payments and performance of other ancillary services relating to the Donnatal product line.

7. Plaintiff Concordia is an international business company incorporated under the law of Barbados, having its principal place of business in Bridgetown, St. Michael, Barbados.

On May 15, 2014, Plaintiff Concordia completed the acquisition of the Donnatal product line from Plaintiff PBM.

8. Upon information and belief, Defendant Method Pharmaceuticals, LLC (“Method”) is a Texas limited liability company with its principal office at 2000 East Lamar Boulevard, Suite 600, Arlington, Texas 76006. Method is the labeler for the Me-PB-Hyos products.

9. The identity of Defendants John Does 1-2 is unknown. John Does 1-2 are the manufacturer and distributor of the Me-PB-Hyos products.

JURISDICTION

10. This Court has subject matter jurisdiction over the claims pursuant to 28 U.S.C. §§ 1331 and 1338. The Court also has supplemental jurisdiction over Plaintiffs’ state and common law claims pursuant to 28 U.S.C. § 1367.

11. Venue is proper in this district pursuant to 28 U.S.C. § 1391. A substantial part of the events giving rise to the claims against Defendants occurred in this District.

12. This Court has personal jurisdiction over Defendants because the Defendants have listed their products for sale in an online database that is used by purchasers of PBA pharmaceuticals in this District, and, accordingly, Defendants have purposefully directed their business activities toward this District. In addition, the Defendants have caused harm to Plaintiffs in this District. Through such conduct, Defendants have purposefully availed themselves of the privileges of conducting business in this District, and, when engaging in such

conduct, it was reasonably foreseeable that Defendants would be subjected to this Court's jurisdiction.

BACKGROUND FACTS

13. According to the National Institute of Health, as many of 30% of Americans suffer from IBS at some point in their lives. IBS can severely compromise an individual's quality of life, and is second only to the common cold as a cause of absenteeism from work.

14. Donnatal is a proprietary combination medicine used as adjunctive therapy in the treatment of IBS, as well as acute enterocolitis. Because Donnatal requires use under the supervision of a healthcare provider, it is available by prescription only.

15. The Donnatal products were first introduced in the market by A.H. Robins Company ("Robins") in 1936. Plaintiff PBM is the successor-in-interest to Robins, and owned and marketed the Donnatal products from 2001 until the acquisition of Donnatal by Plaintiff Concordia on May 15, 2014. Plaintiff PBM retains an interest in the Donnatal products as a 16.17% shareholder of Concordia Healthcare Corp., ultimate parent of Plaintiff Concordia, and as the provider of certain services related to the Donnatal product line.

16. In 1962, when Congress amended the Federal Food, Drug and Cosmetic Act ("FD&C Act"), the Food and Drug Administration (FDA) was required to conduct a retrospective evaluation of drugs that had previously been approved under the FD&C Act between its enactment in 1938 and 1962. Donnatal was one of more than 3,400 drugs affected by this amendment. 21 U.S.C. § 301 et seq.

17. In the 1970s, the FDA began a process of evaluating the safety and efficacy of PBA drug products under the Drug Efficacy Study Implementation (“DESI”) review program. On June 20, 1978, the FDA required any drugs that were involved in the review process to obtain an approved New Drug Application (“NDA”) or Abbreviated New Drug Application (“ANDA”) to remain on the market. 43 Fed. Reg. 26,490 (June 20, 1978).

18. On December 30, 1980 Plaintiffs’ predecessor, Robins, obtained conditional approval ANDAs for its Donnatal Tablets (ANDA 88-676) and Donnatal Elixir (ANDA 86-661). Conditionally approved ANDAs have the same status as safety-only NDAs that had been approved prior to the 1962 Amendments. Drug products manufactured under such a conditionally approved ANDA can be legally marketed until the FDA resolves questions about their effectiveness under the FD&C Act.

19. On May 6, 1983, the FDA published in the Federal Register a notice of an opportunity for a hearing (“NOOH”) regarding the regulatory status of PBA drug products, including Donnatal. Under the FD&C Act, the FDA requires the holders of approved NDAs or those alleging such approvals to submit clinical evidence within 60 days of the NOOH showing that genuine and material issues of fact exist about the effectiveness of the drug that require an administrative hearing for resolution.

20. In response to the NOOH, Robins submitted substantial clinical evidence that raised genuine and material issues supporting the effectiveness of Donnatal.

21. Under the NOOH process, only those companies that actively participated in this hearing process were permitted to legally market their PBA drug products. Plaintiffs’ Donnatal products have been under this NOOH since 1983, and thus have been allowed to continue to

remain on the market pending final resolution of the hearing process. The hearing process for PBA products has not yet been completed.

22. In July 2011, in response to a notice from the FDA seeking clarification of the ownership of Donnatal, Plaintiff PBM submitted information demonstrating that Plaintiff PBM was the successor-in-interest to Robbins, and additional substantial clinical evidence and data supporting the effectiveness of the Donnatal products. This submission further clarified Plaintiff PBM's legal basis for marketing its products.

23. Upon information and belief, Plaintiffs are the only companies that continue to participate in the FDA DESI review process for PBA products.

24. In September 2011, the FDA established a Compliance Policy Guide confirming that any drug product coming to market for the first time after September 19, 2011 alleging any legal status under the DESI review was illegal and subject to immediate legal action by the FDA.

25. Accordingly, upon information and belief, Plaintiffs are the only companies that are legally permitted to market PBA products.

DEFENDANTS' UNLAWFUL CONDUCT

26. On or around April 2, 2014, listings for Defendants' "Me-PB-Hyos Oral Elixir" and "Me-PB-Hyos Oral Tablets" appeared in medical database Medi-Span. Copies of the listings are attached as Exhibit A.

27. Medi-Span is a prescription drug information and interactions database used nationwide by health care professionals, payers and pharmaceutical manufacturers to evaluate

medications that are currently or will soon be on the market. Medi-Span is also used to determine whether generic substitutes are available for brand name products.

28. Pharmaceuticals that are pharmaceutically equivalent are assigned the same Generic Product Identifier (“GPI”) and are “linked” to one another. This linkage information is used by pharmacists, pharmaceutical buyers, and insurance companies to determine whether there are any generic alternatives to a particular brand product.

29. Pharmaceutical equivalence means that the products contain the same active ingredients, in the same amounts, and in the same dosage forms.

30. The Medi-Span listings for “Me-PB-Hyos” show that Defendants’ pharmaceuticals have been “linked” to one another.

31. Accordingly, Defendants claim that their Me-PB-Hyos pharmaceuticals contain ingredients identical to those in Plaintiffs’ Donnatal and that the pharmaceuticals are pharmaceutically equivalent.

32. In addition, by listing their Me-PB-Hyos products on Medi-Span after September 19, 2011, when the FDA unequivocally made approval for new products entering the market mandatory, Defendants claim that their products have been approved by the FDA.

33. In order to be listed in Medi-Span, an applicant must normally submit an FDA Approval Letter and the corresponding approval number. *See* Exhibit B.

34. The FDA would not have provided an Approval Letter or approval number to Defendants because the Defendants do not have an approved NDA or ANDA for their drug products, nor were they participants in the FDA's DESI review process for PBA products.

35. In order to be listed as a DESI drug product, a Medi-Span applicant must show that the drug product may be legally marketed under the FD&C Act. Upon information and belief, Defendants have not submitted any data showing that their Me-PB-Hyos product is approved pursuant to the NOOH record.

36. Defendant Method is listed as the labeler for the Me-PB-Hyos products.

37. The Medi-Span listings do not name the manufacturer(s) and distributor(s) for the drugs, who have been named as Defendants John Does 1 and 2 in this action. Upon information and belief, John Does 1 and 2 have either manufactured and distributed Me-PB-Hyos products, or have agreed to take such actions in the future.

38. Defendants' listings of their Me-PB-Hyos products have been made available to Plaintiffs' customers in this District and have adversely impacted Plaintiffs' sales of their Donnatal products in this District. Upon information and belief, Me-PB-Hyos is not currently available for sale.

39. Accordingly, pharmacists attempting to order Donnatal are unable to fill prescriptions because of the presence of Me-PB-Hyos on Medi-Span as a generic alternative. Pharmacists options' include 1) refusing to fill the patients' prescription, 2) ordering Donnatal at a loss, since the pharmacy will only be reimbursed by insurance companies at the "generic" product rate, despite the fact that no generic is available, 3) participating in a burdensome

“override” process with the insurance companies, or 4) calling the patient’s doctor about ordering a different drug.

40. When pharmacists contact a patient’s doctor regarding ordering a drug other than Donnatal, the doctor is unlikely to prescribe Donnatal in the future, knowing that patients will not be able to easily purchase the PBA pharmaceuticals. These patients (and sales) are likely to be lost to Plaintiffs forever, even though Donnatal may be the preferred prescription for the patient.

41. If Me-PB-Hyos comes onto the market, Plaintiffs will suffer an immediate and substantial loss in market share.

42. In addition, patients will be exposed to a drug that has not been safety-approved by the FDA. Besides the threat to public health, adverse effects may be attributed to Donnatal because patients are often unaware of the substitution, thus resulting in the erosion of Plaintiffs’ goodwill.

43. Defendants’ listings of PBA pharmaceuticals that falsely claim to be pharmaceutically equivalent to Plaintiffs’ Donnatal products is prohibited by law, has caused irreparable injury to Plaintiffs, and will continue to both damage Plaintiffs and to deceive and potentially harm the public unless enjoined by this Court.

44. When the false listing came to Plaintiff PBM’s attention, Plaintiff PBM promptly contacted Defendant Method regarding its unlawful conduct. In response, Defendant claimed that PBA pharmaceuticals are available to be marketed by anyone, and that Plaintiff PBM did not possess the exclusive rights to market these products.

45. Plaintiffs have been and will be harmed by Defendants' false and misleading representations. Defendants' efforts have and will continue to mislead consumers into believing that Me-PB-Hyos is pharmaceutically equivalent to and may be used interchangeably with Donnatal. Defendants' efforts have harmed and will continue to harm Plaintiffs' unique brand, through which purchasers of PBA pharmaceuticals have come to recognize Plaintiffs as the only FDA-approved entities currently allowed to market PBA pharmaceuticals.

COUNT I

FALSE ADVERTISING IN VIOLATION OF LANHAM ACT SECTION 43(a) (15 U.S.C. § 1125(a))

46. Plaintiffs repeat and re-allege each and every allegation contained in the preceding paragraphs of this Complaint, and incorporate them herein by reference.

47. Defendants' representations that Me-PB-Hyos pharmaceuticals are FDA-approved, PBA products substitutable for Donnatal pharmaceuticals based on pharmaceutical equivalency and bioequivalency are false or misleading representations of fact.

48. Defendants' statements have actually deceived or have the tendency to deceive a substantial segment of their audience.

49. Defendants' claims that their goods are a generic alternative for Plaintiffs' Donnatal pharmaceuticals are material and likely to influence the purchasing decisions of health care professionals and patients who consume Plaintiffs' products.

50. Defendants' false or misleading representations were and are made in interstate commerce.

51. Defendants' representations are in direct violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), which provides in relevant part that "[a]ny person who, in connection with any goods or services...uses in commerce any...false or misleading representation of fact, which in commercial advertising or promotion, misrepresents the nature, characteristics, qualities or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act."

52. As a direct and proximate result of Defendants' conduct, Plaintiffs have suffered and are continuing to suffer irreparable injury, including irreparable injury and damages, which includes a loss of sales and profits, which Plaintiffs would have made but for the false and deceptive representations by Defendants.

53. Pursuant to 15 U.S.C. § 1116, Plaintiffs are entitled to preliminary and permanent injunctive relief to Defendants' continuing acts.

COUNT II

UNFAIR COMPETITION IN VIOLATION OF LANHAM ACT SECTION 43(a) (15 U.S.C. § 1125(a))

54. Plaintiffs repeat and re-allege each and every allegation contained in the preceding paragraphs of this Complaint, and incorporate them herein by reference.

55. Plaintiffs' Donnatal has become uniquely associated with and identifies Plaintiffs as the only FDA-approved providers of PBA pharmaceuticals.

56. Defendants' representations that Me-PB-Hyos is pharmaceutically equivalent to Donnatal, and is an FDA-approved PBA pharmaceutical, have deceived, misled and confused consumers and enabled Defendants to trade off of Plaintiffs' reputation and goodwill.

57. Defendants' acts constitute unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

58. By reason of Defendants' conduct, Plaintiffs have suffered and will continue to suffer damage to their business, reputation and goodwill.

59. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Defendants' Lanham Act violations.

60. Defendants' acts are willful, wanton and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Plaintiffs to recover additional damages and their reasonable attorney fees pursuant to 15 U.S.C. § 1117.

61. Defendants' conduct has caused, and unless enjoined by this Court, will continue to cause immediate and irreparable harm to Plaintiffs for which there is no adequate remedy at law. Accordingly, Plaintiffs are additionally entitled to injunctive relief.

COUNT III

VIRGINIA CONSUMER PROTECTION ACT (Va. Code § 59.1-200)

62. Plaintiffs repeat and re-allege each and every allegation contained in the proceeding paragraphs of this Complaint, and incorporate them herein by reference.

63. Defendants, by virtue of their Me-PB-Hyos Medi-Span listings, misrepresent that their pharmaceuticals are pharmaceutically equivalent to and can be used a generic substitute for Donnatal in violation of Va. Code § 59.1-200(5).

64. Defendants, by virtue of their Me-PB-Hyos Medi-Span listings, misrepresent that their pharmaceuticals are approved by the FDA and are legally marketed in violation of Va. Code § 59.1-200(2).

65. As a proximate result of Defendants' misrepresentations, Defendants' conduct has caused, and unless enjoined by this Court, will continue to cause immediate and irreparable harm, for which Plaintiffs are entitled injunctive relief and damages in an amount to be proven at trial.

COUNT IV

COMMON LAW CIVIL CONSPIRACY

66. Plaintiffs repeat and re-allege each and every allegation contained in the preceding paragraphs of this Complaint, and incorporate them herein by reference.

67. Defendants entered into an agreement and/or understanding, and otherwise conspired with one another and others as yet unnamed, to tortuously interfere with Plaintiffs' lawful businesses and misrepresent to the public that they are legally permitted to sell PBA products.

68. As a result of Defendants' actions, Plaintiffs have suffered and are continuing to suffer irreparable injury, including irreparable injury and damages, which includes a loss of sales

and profits which Plaintiffs would have made but for the acts committed in pursuance of the conspiracy.

COUNT V

VIRGINIA BUSINESS CONSPIRACY (Va. Code § 18.2-500)

69. Plaintiffs repeat and re-allege each and every allegation contained in the preceding paragraphs of this Complaint, and incorporate them herein by reference.

70. Defendants have associated, agreed, mutually undertaken or acted in concert together for the purpose of willingly or maliciously harming Plaintiffs' legal businesses. Specifically, Defendants have conspired to falsely represent to the public that they are authorized by the FDA to promote and sell PBA products for the express purpose of interfering with Plaintiffs' current and prospective business relationships.

71. As a result of Defendants' actions, Plaintiffs have suffered and are continuing to suffer irreparable injury, including irreparable injury and damages, which includes a loss of sales and profits which Plaintiffs would have made but for the acts committed in pursuance of the conspiracy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court enter judgment in their favor and grant the following relief:

A. Compensatory damages, consisting of general and special damages, in an amount to be proven at trial, including, but not limited to, treble damages pursuant to Va. Code § 18.2-500;

- B. An award of punitive damages;
- C. A preliminary and permanent injunction permanently enjoining Defendants and all others acting in privity or in concert with them from listing, marketing or offering for sale “Me-PB-Hyos” or other unauthorized PBA pharmaceuticals;
- D. Reasonable attorney fees and costs in prosecuting this action as provided by § 35(a) of the Lanham Act, 15 U.S.C. § 1117 and Virginia law, including, but not limited to, Va. Code § 18.2-500;
- E. Disgorgement of Defendants’ profits from their unlawful acts and an accounting of such profit; and
- F. Award Plaintiffs such other relief as the interests of justice may require.

DATE: June 2, 2014

Respectfully submitted,

PBM PHARMACEUTICALS, INC.

BY: /s/ S. Lloyd Smith

S. Lloyd Smith (VA Bar No. 85119)
Holly B. Lance (VA Bar No. 80595)
BUCHANAN INGERSOLL & ROONEY PC
1737 King Street, Suite 500
Alexandria, Virginia 22314
Tel. (703) 836-6620
Fax: (703) 836-2021
lloyd.smith@bipc.com
holly.lance@bipc.com

Ed John Allera (*pro hac vice* pending)
Theodore M. Sullivan (*pro hac vice* pending)
BUCHANAN INGERSOLL & ROONEY PC
1700 K Street N.W., Suite 300
Washington, District of Columbia 20006
Tel. (202) 452-7900
Fax: (202) 452-7989
edward.allera@bipc.com
theodore.sullivan@bipc.com

*Attorneys for Plaintiffs PBM Pharmaceuticals, Inc.
and Concordia Pharmaceuticals Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of June, 2014, the foregoing **AMENDED COMPLAINT** was filed using the Court's CM/ECF system, and served upon counsel of record for Defendant Method Pharmaceuticals, LLC as follows:

Karla Lynn Palmer
Hyman, Phelps & McNamara, P.C.
700 13th St. NW, Suite 1200
Washington, DC 200005

BY: /s/ S. Lloyd Smith
S. Lloyd Smith (VA Bar No. 85119)
BUCHANAN INGERSOLL & ROONEY PC
1737 King Street, Suite 500
Alexandria, Virginia 22314
Tel. (703) 836-6620
Fax: (703) 836-2021
lloyd.smith@bipc.com

*Attorney for Plaintiffs PBM Pharmaceuticals, Inc.
and Concordia Pharmaceuticals Inc.*